CAUTION: The Handpiece Directions-for-Use are not intended to substitute for the necessity of reading and understanding the driving console Operator’s Manual.

The Handpiece Directions-for-Use include in-depth material intended to familiarize the Operating Room Staff with the controls and functions of the console.

CAUTION: U.S. Federal Law restricts this device to sale by or on the order of a physician.

Step One: Unplug the handpiece connector from the console and install the protective cap.

Step Two: Carefully remove the infusion sleeve and tip from the handpiece using the tip wrench and discard according to surgical facility guidelines.

Step Three: Submerge the nosecone (front part) of the handpiece in a container of room temperature sterile deionized water.

Step Four: Using a syringe, draw or push a minimum of 120cc of sterile deionized water through both the irrigation and aspiration paths.

Step Five: Using the same syringe, flush both ports with a minimum of 60cc of air.

Step Six: Dry the exterior surfaces of the handpiece and cable with a soft clean, lint free non-abrasive cloth.

Step Seven: Place the cleaned handpiece and cable in an autoclavable tray to prevent damage to connector and handpiece during storage and autoclaving or wrap to prevent damage in preparation for autoclaving.

Step Eight: Visually inspect to ensure the Handpiece is clean and dry. Repeat the process as needed.

9. Never immerse the handpiece in liquid after autoclaving; allow it to air cool for at least 15 minutes.

10. During each phaseemulsification procedure, metal particles may result from inadvertent touching of the phaseemulsification tip with a second instrument. Another potential source of metal particles resulting from any ultrasonic handpiece may be the result of ultrasonic energy causing micro abrasions of the ultrasonic tip.

11. If the medical opinion of the physician a patient with a prion related disease undergoes a high risk procedure, the instrument should be destroyed or be processed according to local requirements.

DESCRIPTION: This automated washing procedure provides a method for effectively processing up to three (3) handpieces at a time.

For use of any automated process is required, perform all of the following steps to process the handpiece.

1. If the handpiece is received in a defective condition, do not use and notify Alcon immediately:

   a) Set detergent and neutralizer dispensers as recommended by detergent and washer manufacturer.

   b) Program washer a minimum of 10 minutes (dispense detergent as recommended by detergent and washer manufacturer)

   c) Rinse for a minimum of 5 minutes at 22 - 27°C then drain

   d) Dry at a minimum of 100°C for at least 5 minutes

Note: Additional rinsing steps will not alter the effectiveness of the validated cycle.

- 1 -
Step Eight: Start the wash program. When the wash program is completed, visually inspect to ensure the Handpiece is clean and dry. Repeat the process as needed. Place the processed handpiece and cable in an autoclavable tray to prevent damage to connector and handpiece during storage and autoclaving or wrap to prevent damage in preparation for autoclaving.

4. Sterilization: Sterilize the handpiece using a steam sterilization cycle. The sterilization instructions provided in Table 1 below have been validated by Alcon Laboratories, Inc. as being CAPABLE of sterilizing the Infiniti® Ozil® and U/S Handpieces for re-use. It remains the responsibility of the processor to ensure that the processing as actually performed using equipment, materials and personnel in the facility achieve the desired result. This requires verification and routine monitoring of the process. Likewise any deviation by the processor from the instructions provided should be properly evaluated for effectiveness and potential adverse consequences. Please refer to nationally recognized standards, or to your facility’s standard procedures.

Note: Due to the potential for the accumulation of particulate and bioburden residues in the sterilizer water reservoirs, it is the surgical facility’s responsibility to properly maintain the equipment and their associated filters to ensure the introduction of steam into the Handpiece is contaminant free at levels acceptable per the surgical facility’s requirements.

Table 1 - STERILIZATION TEMPERATURES AND TIME SETTINGS

<table>
<thead>
<tr>
<th>STERILIZER TYPE</th>
<th>PULSES</th>
<th>CONFIGURATION</th>
<th>MINIMUM TEMPERATURE</th>
<th>MINIMUM EXPOSURE TIME (MINUTES)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gravity Displacement</td>
<td>N/A</td>
<td>Wrapped</td>
<td>132° C (270° F)</td>
<td>18</td>
</tr>
<tr>
<td>Gravity Displacement</td>
<td>N/A</td>
<td>Unwrapped</td>
<td>132° C (270° F)</td>
<td>8</td>
</tr>
<tr>
<td>Pulsing Prevacuum</td>
<td>4</td>
<td>Unwrapped</td>
<td>132° C (270° F)</td>
<td>4</td>
</tr>
<tr>
<td>Pulsing Prevacuum</td>
<td>4</td>
<td>Wrapped</td>
<td>134° C (273° F)</td>
<td>5</td>
</tr>
<tr>
<td>Pulsing Prevacuum</td>
<td>4</td>
<td>Wrapped</td>
<td>134-137° C (273-279° F)</td>
<td>3</td>
</tr>
</tbody>
</table>

Note: This product has been validated to perform reliably after steam sterilization at 134°C (273°F) for 18 minutes (prevacuum, wrapped).

5. After transport to the driving console for the next use, refer to your driving console Operator’s Manual for proper surgical setup.
6. Refer to Alcon’s Pack/Tip Directions for Use for proper assembly of the tip to the Handpiece.
7. There are no specific limits for the time or conditions of storage.
8. References:

*EN ISO 17664: Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices.

Definitions for symbols that may appear on product labels:

- **SEE DIRECTIONS FOR USE**
- **DOES NOT CONTAIN LATEX OR DRY NATURAL RUBBER**
- **AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY**